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Abbott RealTime CT/NG
List No. 8L07-91

510(k) Summary

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3.0 Abbott RealTi*me* CT/NG 510(k) Summary

A summary of the Abbott® RealTi*me* CT/NG assay

3.1 Official Correspondent to the File

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3.2 Trade Name:

Abbott RealTi*me* CT/NG (List No. 8L07-91)

3.3 Common Name:

In vitro polymerase chain reaction (PCR) assay for *Chlamydia trachomatis* and *Neisseria gonorrhoeae.*

3.4 Classification Name:

Nucleic acid test (NAT)

3.5 Registration Number and Classification Code:

21 CFR 866.3390 (Class II, Code LSL) describes test reagents used to identifiy Neisseria from clinical specimens.

21 CFR 866.3120 (Class I, Code MKZ) describes test reagents used to identify Chlamydia from clinical specimens.

3.6 Substantially Equivalent Devices

Abbott RealTi*me* CT/NG (List No. 8L07-91) Predicate Devices:

GEN-PROBE APTIMA Combo 2 Assay (Assigned 510(k) No. K043224),

Becton Dickenson ProbeTec ET *Chlamydia trachomatis /Neisseria gonorrhoeae* Amplified DNA Assay (Assigned 510(k) No. K012351).

The Abbott RealTi*me* CT/NG assay was also compared to cell culture methods intended for the qualitative detection of *Neisseria gonorrhoeae.* The predicate culture methods are:

bioMerieux API® NH Assay,

EY Laboratories Gonocheck® II (Assigned 510(k) No. 940162) Assay,

Pharmacia Diagnostics Phadebact® Monoclonal GC test.

3.7 Purpose of the Submission

The purpose of this 510(k) is to gain clearance to market the Abbott RealTi*me* CT/NG (List No. 8L07-91) assay.

3.8 Date of Preparation: August, 2009

3.9 Manufacturer

Abbott Molecular Inc. is the legal manufacturer of the Abbott RealTi*me* CT/NG (List No. 8L07-91) assay and the Abbott *m*ulti-Collect Specimen Collection Kit (List No. 9K12-03).

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3.10 Intended Use

The proposed intended use for the Abbott RealTi*me* CT/NG assay is:

The Abbott RealTi*me* CT/NG (List No. 8L07-91) assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae.* The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.

3.11 Device Description

Abbott RealTi*me* CT/NG consists of two reagent kits:

- Abbott RealTi*me* CT/NG Amplification Reagent Kit (List No. 8L07-91)
- Abbott RealTi*me* CT/NG Control Kit (List No. 8L07-80)

The Abbott RealTi*me* CT/NG assay uses PCR technology with homogenous real-time fluorescence detection on the *m*2000 System. The Abbott *m*2000 System consists of the Abbott *m*2000*sp* and Abbott *m*2000*rt* instruments. The Abbott *m*2000 System integrates sample preparation with nucleic acid amplification and detection to generate assay results. The Abbott *m*2000*sp* is used for processing samples and the Abbott *m*2000*rt* is used for amplification and detection.

3.12 Background on Chlamydia and Gonorrheal Disease

Chlamydia are non-motile, Gram-negative, obligate intracellular parasites of eukaryotic cells. They form inclusions in the cytoplasm of the host cell. *Chlamydia trachomatis* , one of three chlamydial species, is the causative agent of the sexually transmitted disease (STD) chlamydia. Chlamydial infections of the urogenital tract are associated with salpingitis, cervicitis, ectopic pregnancies and tubal factor infertility in women as well as

nongonococcal urethritis and epididymitis in men.[1-4] The genital site most commonly affected in women is the cervix, but the infection can be asymptomatic and, if untreated, is likely to ascend to the uterus, fallopian tubes and ovaries causing pelvic inflammatory disease (PID).[5] Neonates born of infected mothers can contract inclusion conjunctivitis, nasopharyngeal infections, and pneumonia due to *Chlamydia trachomatis* .[6] Infection by *Chlamydia trachomatis* in men is also often asymptomatic and, if untreated, may lead to epididymitis, a major complication.[3] Patients infected with *Chlamydia trachomatis* may be co-infected with *Neisseria gonorrhoeae* , the causative agent of gonorrhea. Further, patients with treatment indications for gonorrhea but not chlamydia often harbor *Chlamydia trachomatis*.[7] Chlamydia infections may not respond well to recommended regimens for treating *Neisseria gonorrhoeae*. Therefore, unless chlamydial infection has been ruled out in patients treated for gonorrhea, dual therapy for gonococcal and chlamydia infections is recommended.[5]

Cell culture, commonly used to detect *Chlamydia trachomatis*, has been replaced by more sensitive nucleic acid tests.[8] Since a specific diagnosis of chlamydia may improve treatment compliance and enhance partner notification, the use of these highly sensitive and specific tests is strongly recommended.[5]

Gonorrhea is one of the most common sexually transmitted diseases in the United States. Over 700,000 new infections of *Neisseria gonorrhoeae* are estimated to occur each year.[9] In men, gonorrhea infection usually results in acute anterior urethritis accompanied by a purulent exudate.[10,11] In women, the infection is most often found in the cervix, but the vagina and uterus also may be infected. Frequently the infection is asymptomatic, especially in women. Without treatment, local complications of gonococcal infection can occur including pelvic inflammatory disease (PID) or acute salpingitis for women and epididymitis for men.[10,11] Rarely, disseminated gonococcal infection, DGI, may occur in untreated patients.[13]

Neisseria gonorrhoeae is a Gram-negative, oxidase-positive diplococcus without flagellae.[12] Culture is commonly used for the detection of *Neisseria gonorrhoeae*. Presumptive diagnosis of gonorrhea is based on the morphological examination, Gram

stain, and oxidase measurement of the culture isolate. Confirmation procedures have been used for definitive identification of *Neisseria gonorrhoeae* including sugar fermentation, fluorescent antibody staining, nucleic acid hybridization, and agglutination.[14,15] Nucleic acid tests are widely available for the sensitive detection of *Neisseria gonorrhoeae* .[8]

3.13 Technological Characteristics of the Device as Compared to the Predicate

The primary functional components of the Abbott RealTi*m*e CT/NG assay are substantially equivalent to other legally marketed nucleic acid amplification tests (NAAT) intended for the qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).

The Abbott RealTi*m*e CT/NG assay has the same general intended uses as the predicate devices. Although there are some technological differences between the Abbott RealTi*m*e CT/NG and the predicate devices, these differences do not raise new types of safety or effectiveness questions.

These devices are similar in that they are designed to prepare nucleic acids for amplification, amplify specific *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) sequences, detect the amplified products, and report qualitative results.

The primary similarities and differences between the Abbott RealTi*m*e CT/NG assay and the NAAT predicate devices are shown in Attachment Tables 3.1 and 3.2.

Table 3.1

Similarities and *Differences* Between Abbott RealTi*me* CT/NG and Nucleic Acid Amplification Predicate Devices

	Current Application	Amplified Nucleic Acid Predicate Devices	
Feature	**Abbott RealTi*me* CT/NG**	**Gen-Probe Aptima Combo 2**	**Becton Dickenson ProbeTec ET**
Intended Use	The Abbott RealTi*me* CT/NG (List No. 8L07-91) assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae*. The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.	The APTIMA Combo 2 Assay is a target amplification nucleic acid probe test that utilizes target capture for the in vitro qualitative detection and differentiation of *ribosomal RNA (rRNA)* from *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* in clinician collected endocervical, vaginal, and male urethral swab specimens, patientcollected vaginal swab specimens, and female and male urine specimens. The assay may be used to test specimens from symptomatic and asymptomatic individuals to aid in the diagnosis of gonococcal and/or chlamydial urogenital disease using the TIGRIS DTS Automated Analyzer or semiautomated instrumentation as specified. *The assay is also intended for use with testing of gynecological specimens collected in the PreservCyt Solution and processed with the Cytyc ThinPrep 2000 System.*	The BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays, when tested with the BD ProbeTec ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral, swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of coinfection with both *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females and males. A separate Amplification Control is an option for inhibition testing (BD ProbeTec ET CT/GC/AC Reagent Pack). The BD ProbeTec ET CT/GC assays may be performed using either the BD ProbeTec ET System or a combination of the BD ProbeTec ET System and BD Viper instrument.

Table 3.2

Similarities and *Differences* Between Abbott RealTi*me* CT/NG and Nucleic Acid Amplification Predicate Devices

Feature	Current Application	Amplified Nucleic Acid Predicate Devices	
	Abbott RealTi*me* CT/NG	**Gen-Probe Aptima Combo 2**	**Becton Dickenson ProbeTec ET**
Assay Type	• Qualitative	• Qualitative	• Qualitative
CT Analyte Targets	• CT cryptic plasmid DNA	• CT *ribosomal RNA*	• CT cryptic plasmid DNA
NG Analyte Targets	• NG genomic DNA	• NG *ribosomal RNA*	• NG genomic DNA
Input Sample Types	• Endocervical swab specimens • Self-collected vaginal swab specimens • Clinician-collected vaginal swab specimens • Male urethral swab specimens • Male and female urine specimens	• Endocervical swab specimens • Self-collected vaginal swab specimens • Clinician-collected vaginal swab specimens • Male urethral swab specimens • Male and female urine specimens • *PreservCyt liquid Pap specimens*	• Endocervical swab specimens • Male urethral swab specimens • Male and female urine specimens
Sample Preparation Procedure	• Automated	• *Semi-automated*/automated	• *Manual/ semi-automated*
Amplification Technology	• Real-time PCR	• *Ribosomal RNA transcriptionmediated amplification (TMA)*	• *Strand displacement DNA amplification (SDA)*
Assay Controls	• Negative Control • Cutoff Control • Internal Control	• Negative Control • *Positive Control*	• Negative Control • *Positive Control* • *Optional Amplification Control*

3.14 Summary of Nonclinical Studies

3.14.1 Analytical Sensitivity

The Limit of Detection (LOD) claim for the Abbott RealTi*m*e CT/NG assay is 320 copies of *Chlamydia trachomatis* (CT) target DNA and 320 copies of *Neisseria gonorrhoeae* (NG) target DNA per assay. The assay targets the *Chlamydia trachomatis* cryptic plasmid (present at approximately 7 to 10 copies per *Chlamydia* organism) and the multicopy opacity gene of *Neisseria gonorrhoeae* (repeated up to 11 times per organism). Thus, 320 copies of target DNA is equivalent to approximately 30 to 40 organisms per assay.

The LOD of the Abbott RealTi*m*e CT/NG assay is defined as CT and NG target DNA concentration detected with a probability of 95% or greater. The CT and NG DNA concentrations detected with 95% probability were determined by testing dilutions of CT and NG target DNA. Probit analysis of the data determined that the concentration of CT DNA detected with 95% probability was 21 copies/assay (95% CI 18 - 28), the concentration of nvCT DNA detected with 95% probability was 29 copies/assay (95% CI 24 - 41), and the concentration of NG DNA detected with 95% probability was 149 copies/assay (95% CI 130 - 176).

The claimed assay LOD was confirmed by testing samples that contained 320 copies of CT, nvCT and NG target DNA per assay. The detection rate was 100% (405/405) for CT, 100% (403/403) for nvCT, and 99.5% (403/405) for NG in the assay.

An additional study was conducted to challenge the performance of the Abbott RealTi*m*e CT/NG assay in samples containing high target numbers of CT, nvCT, or NG in the presence of low target numbers of the opposite analyte. Samples were prepared to contain 320 CT or nvCT target DNA copies and 1×10^7 NG target DNA copies per assay, or 1×10^7 CT or nvCT target DNA copies and 320 NG target DNA copies per assay. The detection rate of 320 copies of CT or nvCT DNA in the presence of high NG target was 100% (405/405). The detection rate of 320 copies of NG DNA in the presence of high CT or nvCT target was 100% (405/405).

The analytical sensitivity of the Abbott RealTi*m*e CT/NG assay for detecting *Chlamydia trachomatis* serovars A through L was determined by testing dilutions of each serovar. Serovars A through K and L1 through L3 were detected at less than 1 Inclusion Forming Units (IFU) per assay. Additionally, nvCT was diluted and was also detected at less than 1 IFU per assay.

The analytical sensitivity of the Abbott RealTi*m*e CT/NG assay for detecting 28 different isolates of *Neisseria gonorrhoeae* was determined by testing dilutions of each isolate. All isolates were detected at less than 1 Colony Forming Unit (CFU)/assay.

3.14.2 Evaluation of Potential Cross-Reactants

A total of 111 strains of bacteria, viruses, parasites, yeast, and fungi were tested for potential cross reactivity in the Abbott RealTi*m*e CT/NG assay (Table 3.6). These included organisms that are phylogenetically related to CT and NG, and those that can be found in the urogenital tract. Purified DNA or RNA was diluted to a final concentration of 1×10^7 copies/assay. HBV DNA and HCV RNA were added directly into the PCR reaction at approximately 4×10^5 and 6×10^6 copies per reaction, respectively. All results were negative for both CT and NG.

Additionally, a total of 32 culture isolates were tested for potential cross reactivity in the Abbott RealTi*m*e assay. These included 27 organisms listed in Table 3.6, and *Neisseria cinerea, Neisseria lactamica, Neisseria sicca*, Ca Ski cells containing HPV 16, and Hela cells containing HPV 18. Ca Ski cells containing HPV 16 and Hela cells containing HPV 18 were tested at 10^6 cells per assay, *C. pneumoniae* and *C. psittaci* were tested at 10^6 EB per assay, HSV-1 and HSV-2 were tested at 10^6 genomes per assay, and the rest of the organisms were tested at 10^6 Colony Forming Units (CFU) per assay. All results were negative for both CT and NG.

Table 3.6

Potentially Cross-Reactive Microorganisms/Viruses

Microorganism/Virus		
Achromobacter xerosis	*Haemophilus ducreyi**	*Proteus vulgaris*
Acinetobacter calcoaceticus	*Haemophilus influenzae*	*Providencia stuartii*
Acinetobacter lwoffii	*Helicobacter pylori*	*Pseudomonas aeruginosa**
Actinomyces israelii	*Hepatitis B virus (HBV)*	*Pseudomonas putida*
Aerococcus viridans	*Hepatitis C virus (HCV)*	*Rahnella aquatilis*
Aeromonas hydrophila	*Herpes Simplex Virus, type I**	*Rhizobium radiobacter*
Alcaligenes faecalis	*Herpes Simplex Virus, type II**	*Rhodospirillum rubrum*
Arcanobacterium pyogenes	*Human immunodeficiency virus (HIV-1)*	*Ruminococcus productus*
Bacillus subtilis	*Human Papilloma Virus 16*	*Salmonella typhimurium*
Bacteroides fragilis	*Human Papilloma Virus 18*	*Salmonella enterica*
Bacteroides ureolyticus	*Kingella denitrificans*	*Serratia marcescens**
Bifidobacterium adolescentis	*Kingella kingae*	*Staphylococcus aureus**
Bifidobacterium breve	*Klebsiella oxytoca*	*Staphylococcus epidermidis**
Brevibacterium linens	*Klebsiella pneumoniae*	*Staphylococcus saprophyticus**
Campylobacter jejuni	*Lactobacillus acidophilus**	*Streptococcus agalactiae**
*Candida albicans**	*Lactobacillus brevis**	*Streptococcus bovis*
Candida glabrata	*Lactobacillus delbrueckii subsp. lactis*	*Streptococcus mitis*
Candida parapsilosis	*Lactobacillus jensenii*	*Streptococcus mutans*
Candida tropicalis	*Legionella pneumophila*	*Streptococcus pneumoniae*
*Chlamydia pneumoniae**	*Listeria monocytogenes*	*Streptococcus pyogenes*
*Chlamydia psittaci**	*Micrococcus luteus**	*Streptococcus salivarius*
Chromobacterium violaceum	*Mobiluncus mulieris*	*Streptococcus sanguinis*
Chryseobacterium meningosepticum	*Moraxella (Branhamella) catarrhalis*	*Streptomyces griseinus*
Citrobacter freundii	*Moraxella lacunata*	*Trichomonas vaginalis*
Clostridium perfringens	*Moraxella osloensis*	*Ureaplasma urealyticum*
*Corynebacterium genitalium**	*Morganella morganii*	*Veillonella parvula*
Corynebacterium xerosis	*Mycobacterium gordonae*	*Vibrio parahaemolyticus*
Cryptococcus neoformans	*Mycobacterium smegmatis**	*Weissella paramesenteroides*
Cytomegalovirus	*Mycoplasma genitalium*	*Yersinia enterocolitica*

* Tested with purified DNA or RNA and with culture isolates.

Table 3.6 (Continued)

Potentially Cross-Reactive Microorganisms/Viruses

Microorganism/Virus	
Deinococcus radiodurans	*Mycoplasma hominis*
Derxia gummosa	*Neisseria flava**
Eikenella corrodens	*Neisseria meningitidis-A**
*Enterobacter cloacae**	*Neisseria meningitidis-B**
Enterobacter aerogenes	*Neisseria meningitidis-C**
Enterococcus avium	*Neisseria meningitidis-D**
*Enterococcus faecalis**	*Neisseria perflava**
Enterococcus faecium	*Pantoea agglomerans*
*Escherichia coli**	*Peptostreptococcus anaerobius*
Fusobacterium nucleatum	*Plesiomonas shigelloides*
Gardnerella vaginalis	*Propionibacterium acnes*
Gemella haemolysans	*Proteus mirabilis**

* Tested with purified DNA or RNA and with culture isolates.

3.14.3 Evaluation of Potentially Interfering Substances

The potential for interference in the Abbott RealTi*me* CT/NG assay was assessed with substances that may be found in swab and/or urine specimens. Substances were spiked into a swab and/or urine matrix containing 320 copies of CT and NG target DNA per assay, and into a swab and/or urine matrix without CT or NG DNA.

No interference in the performance of the Abbott RealTi*me* CT/NG assay was observed in the presence of the substances listed in Table 3.7.

Table 3.7

Substances That Do Not Interfere with the Abbott RealTime CT/NG Assay

Substance	Matrix	Highest Concentration Tested
Zovirax® Cream 5%	Swab	0.25%
CLOTRIMAZOLE Vaginal Cream (2%)	Swab	0.25%
Delfen®	Swab	0.25%
KY® Jelly	Swab	0.25%
Lubrin®	Swab	0.25%
Metrogel-Vaginal®	Swab	0.25%
Miconazole® 3 Suppository	Swab	0.25%
Monostat-1™ Dose Treatment (tioconazole ointment)	Swab	0.25%
Norforms® Deodorant Suppositories	Swab	0.25%
Terazol-3® Vaginal Cream	Swab	0.25%
Vagi gard® Povidone-Iodine Medicated Douche	Swab	0.25%
Vagi gard® Moisturizing Gel	Swab	0.25%
Vagisil® Anti-itch Creme	Swab	0.25%
Vagisil® Intimate Lubricant	Swab	0.25%
Yeast gard®	Swab	0.25%
Bilirubin	Urine	10 mg/mL
Glucose	Urine	10 mg/mL
pH 4 (acidic) Urine	Urine	N/A
pH 9 (alkaline) Urine	Urine	N/A
Protein: BGG	Urine	5%
Blood	Swab and Urine	5%
Leukocytes	Swab and Urine	1×10^6 cell/mL

Interference in the performance of the Abbott RealTi*m*e CT/NG assay may be observed with the following substances:

- Talcum powder at concentrations greater than 0.1% in urine specimens.
- Phenazopyridine hydrochloride (the active ingredient in URISTAT) at concentrations greater than 3 mg/mL in urine specimens.
- Mucus at concentrations greater than 0.1% for urine specimens and 1% for swab specimens.

3.14.4 Carryover

Potential carryover was determined by performing a study in which high copy CT positive samples were interspersed with negative samples arranged in a checkerboard pattern. The positive samples were CT DNA at a concentration of 10^7 copies/ml. The carryover rate is defined as the number of CT negative samples that are reported as positive or equivocal over the total number of CT-negative samples tested. Each run included 47 negative samples and 46 positive samples. A total of 14 runs were evaluated using two lots of the RealTi*m*e CT/NG amplification reagents on four *m*2000*sp* and *m*2000*rt* instrument pairs.

A total of 656 valid negative samples were evaluated for potential carryover effect. A total of 5 false positive and 1 equivocal results were observed. The carryover rate was 0.91%.

3.14.5 Precision Study

A precision study was performed at three sites, two external and one internal. Each site was provided a fifteen-member panel. Nine panel members targeted different combinations of CT and NG concentrations and six panel members targeted different combinations of nvCT and NG concentrations. The source material for CT was Vero/LGV-II, strain 434. The source material for nvCT was strain 68226. The source material for NG was ATCC isolate 27628 and 31426. Five replicates of each panel member were tested in each run. Thirty runs (10 per site) were performed for a total of 150 replicates of each panel member. The study included three amplification reagent lots. Each site tested two amplification reagent lots. A variance components analysis for a nested model was performed on delta cycle (DC) values, and the results are summarized in Tables 3.8 and 3.9, respectively.

Table 3.8

Precision Study: CT Results

Panel Member[a]	No. Tested[b]	No. Positive	Mean Delta Cycle	Within-Run Component SD[c]	Between-Run Component SD[c]	Between-Lot Component SD[c]	Between-Site Component SD[c]	Total SD[c,d]
1	150	150	15.29	0.265	0.204	0.110	0.135	0.377
2	150	150	15.67	0.411	0.245	0.000	0.179	0.511
3	150	150	3.75	0.466	0.234	0.255	0.000	0.581
4	150	150	9.45	0.503	0.103	0.022	0.000	0.514
5	150	0	...	...	...	...	...	...
6	149	149	17.35	0.229	0.193	0.153	0.159	0.371
7	150	0	...	...	...	...	...	...
8	147	0	...	...	...	...	...	...
9	150	125	1.59	0.674	0.248	0.312	0.000	0.783
10	149	149	15.69	0.334	0.250	0.205	0.286	0.545
11	150	150	15.59	0.428	0.180	0.216	0.289	0.588
12	150	140	3.79	0.461	0.458	0.329	0.000	0.728
13	150	150	9.02	0.269	0.274	0.165	0.261	0.493
14	150	150	15.63	0.284	0.265	0.109	0.413	0.578
15	147	50	1.81	0.575	0.376	0.518	0.000	0.860

[a] *Chlamydia trachomatis* (CT) concentrations were targeted approximately to 4500 IFU/assay in members 1, 2, and 6 and to 45 IFU/assay in member 4. Member 3 was targeted approximately to 0.75 IFU/assay and member 9 to 0.2 IFU/assay both below the claimed assay LOD. New variant strain (nvCT) concentrations were targeted approximately to 50 IFU/assay in members 10, 11, and 14 and 1 IFU/assay in member 13. Members 12 and 15 were targeted to less than 0.1 IFU/assay, below the claimed assay LOD. Members 5, 7, and 8 did not contain any CT or nvCT organisms.

[b] Invalid replicates were excluded from the analysis.

[c] The SD is based on positive replicates only. For member 9, analysis of all replicates with a cycle number (n=133), including those beyond the assay cutoff, resulted in a total SD of 0.960. For member 15, analysis of all replicates with a cycle number (n=52), including those beyond the assay cutoff, resulted in a total SD of 1.037.

[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

Table 3.9

Precision Study: NG Results

Panel Member[a]	No. Tested[b]	No. Positive	Mean Delta Cycle	Within-Run Component SD[c]	Between-Run Component SD[c]	Between-Lot Component SD[c]	Between-Site Component SD[c]	Total SD[c,d]
1	150	150	13.32	0.295	0.157	0.048	0.000	0.337
2	150	150	7.64	0.419	0.182	0.000	0.123	0.473
3	150	150	8.03	0.288	0.146	0.000	0.000	0.323
4	149	0	...	...	...	...	...	...
5	150	150	7.59	0.245	0.184	0.028	0.000	0.308
6	149	0	...	...	...	...	...	...
7	150	150	13.45	0.512	0.105	0.133	0.000	0.539
8	147	0	...	...	...	...	...	...
9	150	69	0.51	0.326	0.000	0.000	0.029	0.327
10	149	149	13.29	0.207	0.147	0.051	0.213	0.335
11	150	150	7.27	0.271	0.159	0.046	0.110	0.336
12	150	150	7.24	0.220	0.180	0.000	0.088	0.297
13	150	0	...	...	...	...	...	...
14	150	0	...	...	...	...	...	...
15	147	47	0.50	0.348	0.102	0.000	0.103	0.377

[a] *Neisseria gonorrhoeae* (NG) concentrations were targeted approximately to 2000 CFU/assay in members 1, 7, and 10; to 20 to 50 CFU/assay in members 2, 3, 5, 11, and 12. Members 9 and 15 were targeted to 0.1 CFU/assay, below the claimed assay LOD. Members 4, 6, 8, 13, and 14 did not contain any NG organisms.

[b] Invalid replicates were excluded from the analysis.

[c] For member 9, analysis of all replicates with a cycle number (n=147), including those beyond the assay cutoff, resulted in a total SD of 1.156. For member 15, analysis of all replicates with a cycle number (n=138), including those beyond the assay cutoff, resulted in a total SD of 1.201.

[d] The total variability contains within-run, between-run, between-lot, and between-site variability.

3.15 Summary of Clinical Studies

Performance characteristics of the Abbott RealTi*m*e CT/NG assay were established in a multi-center clinical study conducted in the United States. Specimens were collected from subjects at 16 geographically diverse sites that included physician private practices, public and private STD clinics, and a hospital emergency room. A total of 3,832 male and female, asymptomatic and symptomatic subjects were enrolled. Study subjects were classified as symptomatic if the subject reported STD-related symptoms. Specimens collected from each female subject included urine, endocervical swabs, self-collected vaginal swab, and clinician-collected vaginal swabs. Specimens collected from each male subject included urine and urethral swabs. Specimen testing methods included the Abbott RealTime CT/NG assay, two commercially available nucleic acid amplification tests (NAAT) for CT and NG, and culture for NG. The NAATs and the NG culture were used as reference assays in the clinical study.

For females, self-collected vaginal swab and urine specimens were collected first, followed by endocervical swab for culture. Remaining swab specimen collection was randomized to minimize bias. For males, urethral swab for culture was collected first. Remaining swab specimen collection was randomized to minimize bias. Urine specimen was collected after the swab specimens.

For each subject, a patient infected status was determined based on the combined results from the reference assays. A female subject was categorized as infected for CT or NG if a minimum of two positive results (at least one from each reference NAAT) was reported. For CT, female subjects with positive results on both reference urine specimens and negative results on all three reference swab specimens (clinician-collected vaginal swab from NAAT 1 and endocervical swab specimens from both reference assays) were categorized as infected for urine and not infected for swab specimens. A male subject was categorized as infected for CT or NG if a minimum of two positive results was reported. If the reference NG culture assay result was positive, the subject was categorized as infected regardless of NAAT results.

A female subject was categorized as not infected with CT or NG if at least one of the reference NAATs reported negative results for all sample types and if the NG culture assay result was negative. A male subject was categorized as not infected with CT or NG if a total of at least two negative results were reported by the reference NAATs and if the NG culture assay result was negative.

If patient infected status could not be determined due to missing and/or indeterminate results from the reference assays, the subject was excluded from the analysis. Patient infected status could not be determined for 4 subjects for CT and 7 subjects for NG.

Tables 3.10 through 3.28 summarize the clinical trial data.

Abbott RealTi*m*e CT/NG test results were compared to the patient infected status for calculation of assay sensitivity and specificity. A total of 6,555 CT and 6,569 NG results were used in the analysis. The results were analyzed by gender, sample type, and the presence of symptoms. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and specificity for NG was 97.5% and 99.7%, respectively. Sensitivity and specificity for CT for female subjects and male subjects are presented in Tables 3.10 and 3.11, respectively. Sensitivity and specificity for NG for female subjects and male subjects are presented in Tables 3.12 and 3.13, respectively.

A comparison of patient infected status, individual test results from the reference assays and Abbott RealTi*m*e CT/NG assay was performed. CT results for infected and non-infected female subjects are presented in Tables 3.14 and 3.15, and for infected and non-infected male subjects in Tables 3.16 and 3.17. NG results for infected and non-infected female subjects are presented in Tables 3.18 and 3.19, and for infected and non-infected male subjects in Tables 3.20 and 3.21.

The prevalence of CT and NG in this study was dependent on several factors including age, gender, clinic type, and the method of testing. The prevalence per collection site determined by the Abbott RealTi*m*e CT/NG assay for endocervical swab specimens is presented in Table 3.22, for clinician-collected and self-collected vaginal swab specimens

is presented in Table 3.23; for female urine specimens in Table 3.24; and for male urethral swab and male urine specimens in Tables 3.25 and 3.26, respectively.

The Positive and Negative Predictive Values (PPV and NPV) were calculated using hypothetical prevalence rates and the Abbott RealTi*m*e CT/NG assay sensitivity and specificity determined from the clinical study. The overall sensitivity and specificity for CT was 95.2% and 99.3%, respectively. The overall sensitivity and specificity for NG was 97.5% and 99.7%, respectively. Estimates of the PPV and NPV for the Abbott RealTi*m*e CT/NG assay are presented in Table 3.27 for CT and Table 3.28 for NG.

Table 3.10

***Chlamydia trachomatis* Clinical Sensitivity and Specificity**
Female Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Endocervical Swab	Symptomatic	616	60	1	551	4	93.8	(84.8, 98.3)	99.8	(99.0, 100.0)
Clinician-Collected Vaginal Swab	Symptomatic	615	63	0	551	1	98.4	(91.6, 100.0)	100.0	(99.3, 100.0)
	Asymptomatic	594	35	4	554	1	97.2	(85.5, 99.9)	99.3	(98.2, 99.8)
Self-Collected Vaginal Swab	Symptomatic	587	62	6	518	1	98.4	(91.5, 100.0)	98.9	(97.5, 99.6)
	Asymptomatic	586	36	5	544	1	97.3	(85.8, 99.9)	99.1	(97.9, 99.7)
Urine	Symptomatic	737	73	2	655	7	91.3	(82.8, 96.4)	99.7	(98.9, 100.0)
	Asymptomatic	686	43	2	638	3	93.5	(82.1, 98.6)	99.7	(98.9, 100.0)

Table 3.11

***Chlamydia trachomatis* Clinical Sensitivity and Specificity**
Male Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Urethral Swab	Symptomatic	669	128	9	523	9	93.4	(87.9, 97.0)	98.3	(96.8, 99.2)
Urine	Symptomatic	822	171	6	637	8	95.5	(91.4, 98.1)	99.1	(98.0, 99.7)
	Asymptomatic	643	84	4	552	3	96.6	(90.3, 99.3)	99.3	(98.2, 99.8)

Table 3.12

***Neisseria gonorrhoeae* Clinical Sensitivity and Specificity**
Female Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Endocervical Swab	Symptomatic	619	22	1	593	3	88.0	(68.8, 97.5)	99.8	(99.1, 100.0)
Clinician-Collected Vaginal Swab	Symptomatic	616	26	0	589	1	96.3	(81.0, 99.9)	100.0	(99.4, 100.0)
	Asymptomatic	593	17	0	576	0	100.0	(80.5, 100.0)	100.0	(99.4, 100.0)
Self-Collected Vaginal Swab	Symptomatic	589	25	2	561	1	96.2	(80.4, 99.9)	99.6	(98.7, 100.0)
	Asymptomatic	587	17	0	570	0	100.0	(80.5, 100.0)	100.0	(99.4, 100.0)
Urine	Symptomatic	736	30	3	701	2	93.8	(79.2, 99.2)	99.6	(98.8, 99.9)
	Asymptomatic	687	19	3	661	4	82.6	(61.2, 95.0)	99.5	(98.7, 99.9)

Table 3.13

***Neisseria gonorrhoeae* Clinical Sensitivity and Specificity**
Male Specimens

Specimen	Symptoms	n	True Pos	False Pos	True Neg	False Neg	Sensitivity (95% C.I.)		Specificity (95% C.I.)	
Urethral Swab	Symptomatic	676	188	5	482	1	99.5	(97.1, 100.0)	99.0	(97.6, 99.7)
Urine	Symptomatic	823	228	5	587	3	98.7	(96.3, 99.7)	99.2	(98.0, 99.7)
	Asymptomatic	643	11	0	632	0	100.0	(71.5, 100.0)	100.0	(99.4, 100.0)

Table 3.14
CT Analysis According to Patient Infected Status
INFECTED FEMALE Subjects

NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
+	+	+	+	+	+	+	+	+	38	24	62
+	+	+	+	NA	+	+	+	+	1	0	1
+	+	+	+	NA	+	+	NA	+	1	0	1
+	+	+	+	NA	+	NA	NA	+	1	0	1
+	+	NA	+	NA	+	+	+	NA	0	1	1
+	+	+	+	+	+	+	NA	+	4	2	6
+	+	+	+	+	+	NA	+	+	2	1	3
+	+	+	+	+	NA	+	+	+	4	2	6
+	+	+	+	+	+	NA	NA	+	1	0	1
+	+	+	+	+	NA	+	NA	+	1	0	1
+	+	+	+	+	NA	NA	+	+	1	0	1
+	+	+	+	+	NA	NA	NA	+	3	1	4
+	+	+	+	–	+	+	+	+	1	2	3
+	+	+	–	+	+	+	+	+	1	2	3
+	+	+	–	+	NA	NA	NA	+	1	0	1
+	–	+	+	+	+	+	+	+	2	0	2
+	+	–	+	–	+	+	+	+	1	0	1
–	+	+	–	+	NA	+	+	+	0	1	1
–	+	–	+	+	+	+	+	+	1	0	1
–	+	–	+	+	NA	+	+	+	1	0	1
–	–	+	–	+	NA	NA	NA	+	0	1	1
+	+	+	NA	+	+	+	NA	–	1	0	1
+	+	+	+	–	NA	NA	+	–	1	0	1
+	+	+	+	–	+	+	+	–	3	0	3
+	+	–	+	NA	+	+	+	–	1	0	1
+	+	–	+	–	+	+	+	–	1	0	1
+	+	–	+	–	NA	NA	NA	–	0	1	1
–	+	–	+	–	NA	NA	+	–	0	1	1
+	+	+	+	+	–	+	+	+	1	1	2
+	+	+	–	+	–	NA	NA	+	1	0	1
–	+	+	–	+	–	NA	+	+	2	0	2
–	–	+	–	+	–	NA	+	+	1	1	2
–	+	–	–	+	–	NA	+	–	0	1	1
+	–	+	–	+	NA	–	–	+	1	0	1
–	–	+	NA	+	–	–	–	+	0	1	1
–	–	+	–	+	–	–	–	+	2	4	6

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

* Subjects with positive results on both reference urine specimens and negative results on all three reference swab specimens (clinician-collected vaginal swab from NAAT 1 and endocervical swab specimens from both reference assays) were categorized as infected for urine and not infected for swab specimens.

Table 3.15

CT Analysis According to Patient Infected Status
NON-INFECTED FEMALE Subjects

NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
–	–	–	–	–	–	–	–	–	392	414	806
–	–	–	–	NA	–	–	–	–	43	24	67
–	–	–	–	NA	–	–	–	NA	1	0	1
–	–	–	–	NA	–	–	NA	–	2	3	5
–	–	–	–	NA	–	NA	–	–	3	3	6
–	–	–	–	NA	NA	–	–	–	4	1	5
–	–	–	–	NA	NA	–	–	NA	1	1	2
–	–	–	–	NA	–	NA	NA	–	1	1	2
–	–	–	–	NA	NA	NA	NA	–	7	2	9
–	–	–	NA	–	–	–	–	–	9	24	33
–	–	–	NA	–	–	–	NA	–	0	1	1
–	–	–	NA	–	–	NA	–	–	0	1	1
–	–	–	NA	–	NA	–	–	–	0	1	1
–	–	–	NA	–	NA	NA	NA	–	0	2	2
–	–	NA	–	–	–	–	–	–	0	1	1
–	NA	–	–	–	–	–	–	–	0	1	1
–	NA	–	–	–	NA	–	NA	–	0	1	1
NA	–	–	–	–	–	NA	–	–	0	1	1
–	–	–	–	–	–	–	–	NA	2	7	9
–	–	–	–	–	–	–	NA	–	49	32	81
–	–	–	–	–	–	NA	–	–	20	25	45
–	–	–	–	–	NA	–	–	–	22	19	41
–	–	–	–	–	–	–	NA	NA	1	2	3
–	–	–	–	–	NA	–	–	NA	2	1	3
–	–	–	–	–	–	NA	NA	–	6	3	9
–	–	–	–	–	NA	–	NA	–	7	5	12
–	–	–	–	–	NA	NA	–	–	6	3	9
–	–	–	–	–	NA	NA	NA	–	64	50	114
–	–	–	–	+	–	–	–	–	1	1	2
–	–	–	–	+	–	NA	–	–	0	1	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.15 (Continued)

CT Analysis According to Patient Infected Status
NON-INFECTED FEMALE Subjects

NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
–	–	–	NA	+	–	–	–	–	1	0	1
–	–	–	+	–	–	–	–	–	3	0	3
–	–	–	+	NA	–	–	–	–	0	1	1
–	–	–	+	–	–	NA	–	–	2	0	2
–	–	–	+	–	NA	NA	NA	–	1	0	1
–	–	+	–	–	–	–	–	–	0	2	2
–	–	+	–	–	–	–	–	NA	0	1	1
–	–	+	–	–	NA	NA	NA	–	1	0	1
–	+	–	–	–	–	–	–	–	2	2	4
–	+	–	–	–	–	–	NA	–	1	0	1
–	+	–	–	–	–	NA	NA	–	1	1	2
–	+	–	–	–	–	NA	NA	NA	0	1	1
+	–	–	–	–	–	–	–	–	2	2	4
+	+	–	–	–	–	NA	NA	–	1	0	1
+	+	–	–	–	NA	NA	NA	–	0	2	2
–	–	–	–	NA	–	–	–	+	0	1	1
–	–	–	–	–	–	–	+	–	2	1	3
–	–	–	–	NA	–	–	+	–	1	0	1
–	–	–	–	–	–	+	NA	–	0	1	1
–	–	+	–	–	–	–	–	+	0	1	1
–	+	–	–	–	–	NA	+	–	1	0	1
–	+	–	–	–	+	NA	NA	–	0	1	1
–	+	+	–	–	–	–	NA	+	1	0	1
–	+	+	–	–	NA	NA	NA	+	1	0	1
+	+	–	–	–	–	+	–	–	0	1	1
+	+	–	–	–	+	NA	NA	–	0	1	1
+	+	–	–	–	+	+	+	–	0	2	2
+	+	+	–	–	+	NA	+	–	0	1	1
+	+	+	–	–	+	NA	+	NA	1	0	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.16

CT Analysis According to Patient Infected Status
INFECTED MALE Subjects

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (MSU/MU)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	114	56	170
+	+	+	+	NA	1	0	1
+	+	+	NA	+	30	12	42
+	+	NA	+	+	5	1	6
+	+	NA	NA	+	2	1	3
+	+	–	+	+	5	3	8
+	+	–	NA	+	5	0	5
+	–	+	+	+	1	0	1
–	+	+	+	+	0	1	1
NA	+	+	NA	+	1	0	1
–	+	+	NA	+	0	2	2
+	+	+	–	+	5	3	8
–	+	+	–	+	3	5	8
+	+	+	+	–	1	1	2
+	+	+	NA	–	3	0	3
+	+	–	+	–	1	0	1
+	+	–	NA	–	2	0	2
+	–	+	NA	–	0	1	1
+	+	–	–	–	1	1	2

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.17

CT Analysis According to Patient Infected Status
NON-INFECTED MALE Subjects

NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MU	MU	MUS	MU	Symptomatic (MSU/MU)	Asymptomatic (Urine Only)	Total
–	–	–	–	–	479	421	900
–	–	–	–	NA	6	2	8
–	–	–	NA	–	100	83	183
–	–	NA	–	–	25	36	61
–	–	NA	NA	–	8	4	12
–	NA	–	–	–	1	0	1
NA	–	–	NA	–	1	0	1
–	–	+	–	–	3	0	3
–	+	–	–	–	3	2	5
+	–	–	–	–	4	0	4
–	–	+	NA	–	1	2	3
–	+	–	NA	–	1	0	1
+	–	–	NA	–	3	4	7
–	–	–	+	–	5	0	5
–	–	+	+	–	1	0	1
+	–	–	+	–	2	0	2
–	–	–	–	+	2	0	2
–	–	–	NA	+	2	1	3
–	–	+	NA	+	0	1	1
–	+	–	–	+	0	1	1
+	–	–	NA	+	1	1	2
–	–	+	+	+	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.18

NG Analysis According to Patient Infected Status
INFECTED FEMALE Subjects

Culture	NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
+	+	+	+	+	+	+	+	+	+	9	6	15
+	+	+	+	+	NA	+	+	NA	+	1	0	1
+	+	+	+	+	+	+	+	NA	+	1	1	2
+	+	+	+	+	+	+	NA	+	+	0	1	1
+	+	+	+	+	+	NA	+	+	+	1	0	1
+	+	+	+	+	+	NA	NA	NA	+	2	0	2
−	+	+	+	+	+	+	+	+	+	4	5	9
−	+	+	+	+	+	+	NA	+	+	0	1	1
−	+	+	+	+	+	NA	+	+	+	0	1	1
−	+	+	+	+	+	+	NA	NA	+	0	1	1
−	+	+	+	+	−	+	+	+	+	3	0	3
−	+	+	+	+	−	NA	NA	NA	+	1	0	1
−	+	+	+	−	+	NA	+	+	+	1	0	1
+	−	+	−	+	+	+	+	+	+	1	0	1
−	+	+	−	+	NA	NA	NA	NA	+	1	0	1
−	+	+	−	−	+	NA	+	+	+	1	0	1
−	+	−	+	−	+	+	NA	+	+	1	0	1
−	−	+	−	+	NA	NA	+	+	+	0	1	1
−	−	−	+	−	+	NA	NA	NA	+	0	1	1
+	+	+	+	+	−	NA	NA	NA	−	0	1	1
+	+	+	−	+	NA	+	NA	NA	−	0	1	1
+	+	+	−	+	−	+	+	NA	−	0	1	1
−	+	+	+	+	−	+	+	+	−	1	0	1
−	+	+	−	+	−	+	+	+	−	1	1	2
−	+	+	+	+	+	−	+	+	+	1	0	1
−	NA	+	+	−	+	−	+	+	+	0	1	1
−	−	+	−	+	−	−	+	+	+	1	0	1
−	−	−	+	−	+	−	−	−	+	1	0	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.19

NG Analysis According to Patient Infected Status
NON-INFECTED FEMALE Subjects

Culture	NAAT 1			NAAT 2		RealTi*me* CT/NG				No. of Subjects		
E	E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
–	–	–	–	–	–	–	–	–	–	409	423	832
–	–	–	–	–	NA	–	–	–	–	52	27	79
–	–	–	–	–	NA	–	–	NA	–	2	3	5
–	–	–	–	–	NA	–	NA	–	–	4	3	7
–	–	–	–	–	NA	NA	–	–	–	4	0	4
–	–	–	–	–	NA	NA	–	–	NA	1	0	1
–	–	–	–	–	NA	–	NA	NA	–	1	1	2
–	–	–	–	–	NA	NA	NA	NA	–	6	2	8
–	–	–	–	NA	–	–	–	–	–	7	24	31
–	–	–	–	NA	–	–	–	NA	–	1	1	2
–	–	–	–	NA	–	NA	NA	NA	–	0	2	2
NA	–	–	–	NA	–	–	–	–	–	0	2	2
NA	–	–	–	NA	–	–	NA	–	–	0	1	1
NA	–	–	–	NA	–	NA	–	–	–	0	1	1
–	–	NA	–	–	–	–	–	–	–	0	1	1
–	–	NA	–	–	–	NA	–	NA	–	0	1	1
NA	–	NA	–	–	–	–	–	–	–	0	1	1
–	NA	–	–	–	–	–	NA	–	–	0	1	1
NA	–	–	–	–	–	–	–	–	–	1	0	1
NA	–	–	–	–	–	–	–	NA	–	0	1	1
–	–	–	–	–	–	–	–	–	NA	4	9	13
–	–	–	–	–	–	–	–	NA	–	50	28	78
–	–	–	–	–	–	–	NA	–	–	22	26	48
–	–	–	–	–	–	NA	–	–	–	21	19	40
–	–	–	–	–	–	–	–	NA	NA	1	3	4
–	–	–	–	–	–	–	NA	–	NA	1	0	1
–	–	–	–	–	–	NA	–	–	NA	1	1	2
–	–	–	–	–	–	–	NA	NA	–	9	4	13
–	–	–	–	–	–	NA	–	NA	–	6	4	10
–	–	–	–	–	–	NA	NA	–	–	7	4	11

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.19 (Continued)

NG Analysis According to Patient Infected Status
NON-INFECTED FEMALE Subjects

Culture	NAAT 1			NAAT 2		RealTime CT/NG				No. of Subjects		
E	E	CCV	FU	E	FU	E	CCV	SCV	FU	Symptomatic (E/SCV/CCV/FU)	Asymptomatic (SCV/CCV/FU)	Total
–	–	–	–	–	–	NA	NA	NA	–	59	50	109
–	–	–	–	–	+	–	–	–	–	17	13	30
–	–	–	–	–	+	–	–	NA	–	2	1	3
–	–	–	–	–	+	–	NA	–	–	2	1	3
–	–	–	–	–	+	NA	–	–	–	1	0	1
–	–	–	–	–	+	NA	–	NA	–	1	0	1
–	–	–	–	–	+	NA	NA	NA	–	6	4	10
–	–	–	–	+	–	–	–	–	–	1	6	7
–	–	–	–	+	–	NA	NA	–	–	1	0	1
–	–	–	–	+	NA	–	–	–	NA	1	0	1
–	–	–	+	–	–	–	–	–	–	1	0	1
–	–	–	+	–	–	–	–	NA	–	0	1	1
–	–	+	–	–	–	–	–	–	–	1	1	2
–	–	+	–	–	–	NA	NA	NA	–	1	0	1
–	+	–	–	–	–	–	–	NA	–	1	0	1
–	+	–	–	–	–	NA	–	NA	–	0	1	1
–	+	–	–	–	–	NA	NA	NA	–	2	0	2
–	–	–	–	+	+	–	–	–	–	0	1	1
–	+	+	–	–	–	–	NA	–	–	0	1	1
–	–	–	–	–	–	–	–	–	+	1	0	1
–	–	–	–	–	–	NA	NA	NA	+	1	0	1
–	–	–	+	–	–	–	–	–	+	0	3	3
–	+	+	+	–	–	NA	NA	NA	+	1	0	1
–	–	+	–	–	–	–	–	+	–	1	0	1
–	–	+	+	–	–	–	NA	+	–	1	0	1
–	–	–	–	–	–	+	–	–	–	1	0	1
–	–	–	–	–	–	+	NA	–	–	0	1	1

E = Endocervical Swab Specimen; CCV = Clinician-Collected Vaginal Swab Specimen;
FU = Female Urine Specimen; SCV = Self-Collected Vaginal Swab Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.20

NG Analysis According to Patient Infected Status
INFECTED MALE Subjects

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MUS	MU	MU	MUS	MU	Symptomatic (MSU/MU)	Asymptomatic (Urine Only)	Total
+	+	+	+	+	+	140	1	141
+	+	+	+	NA	+	32	1	33
+	+	+	NA	+	+	2	1	3
+	+	NA	+	+	+	1	0	1
+	+	NA	NA	+	NA	1	0	1
NA	+	+	+	+	+	2	0	2
NA	+	+	+	NA	+	4	0	4
+	+	+	–	+	+	8	0	8
+	+	–	+	+	+	2	0	2
–	+	+	+	+	+	27	4	31
–	+	+	+	NA	+	5	2	7
–	+	+	NA	+	+	1	0	1
–	NA	+	+	NA	+	1	0	1
–	+	+	NA	NA	+	1	0	1
–	+	+	–	+	+	1	0	1
+	–	–	+	+	+	1	0	1
–	–	+	+	+	+	0	1	1
+	+	–	–	+	–	1	0	1
–	+	+	+	+	–	1	0	1
–	–	+	+	–	+	0	1	1
+	–	–	–	–	–	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.21

NG Analysis According to Patient Infected Status
NON-INFECTED MALE Subjects

Culture	NAAT 1		NAAT 2	RealTime CT/NG		No. of Subjects		
MUS	MUS	MU	MU	MUS	MU	Symptomatic (MSU/MU)	Asymptomatic (Urine Only)	Total
–	–	–	–	–	–	418	456	874
–	–	–	NA	–	–	32	36	68
–	–	–	NA	NA	–	9	6	15
–	NA	–	–	–	–	1	1	2
–	NA	–	–	NA	–	1	0	1
NA	–	–	–	–	–	7	6	13
–	–	–	–	–	NA	7	2	9
–	–	–	–	NA	–	96	96	192
–	–	–	+	–	–	13	21	34
NA	–	–	+	–	–	0	1	1
–	–	–	+	NA	–	3	4	7
–	–	+	–	–	–	2	2	4
–	–	+	–	NA	–	0	1	1
–	+	–	–	–	–	2	2	4
–	–	–	–	+	–	1	0	1
–	+	–	–	+	–	2	0	2
–	–	–	–	NA	+	3	0	3
–	–	–	+	+	+	1	0	1
–	+	–	–	+	+	1	0	1

MUS = Male Urethral Swab Specimen; MU = Male Urine Specimen.
NA includes "indeterminate" results from reference assays, specimens not available, or missing results.

Table 3.22

Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site: Symptomatic Female Endocervical Specimens

	Female Endocervical					
	% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]	
1	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)
3	3.2	(2/63)	6.3	(4/63)	1.6	(1/63)
4	0.0	(0/26)	11.5	(3/26)	0.0	(0/26)
5	0.0	(0/12)	0.0	(0/12)	0.0	(0/12)
6	0.0	(0/8)	12.5	(1/8)	0.0	(0/8)
7	2.3	(4/172)	9.3	(16/172)	2.3	(4/172)
8	0.0	(0/38)	7.9	(3/38)	2.6	(1/38)
9	7.7	(3/39)	15.4	(6/39)	0.0	(0/39)
10	2.6	(3/116)	6.9	(8/116)	2.6	(3/116)
11	3.4	(1/29)	17.2	(5/29)	3.4	(1/29)
12	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)
13	0.0	(0/16)	0.0	(0/16)	0.0	(0/16)
14	0.0	(0/34)	2.9	(1/34)	0.0	(0/34)
15	3.8	(1/26)	0.0	(0/26)	0.0	(0/26)
16	0.0	(0/10)	0.0	(0/10)	0.0	(0/10)
All	2.3	(14/616)	7.6	(47/616)	1.6	(10/616)

[a] No evaluable results were available from Site 2.
[b] Does not include specimens that were positive for both CT and NG.

Table 3.23

Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site:
Symptomatic and Asymptomatic Clinician-Collected and Self-Collected Vaginal Swab Specimens

	Clinician-Collected Vaginal Swab						Self-Collected Vaginal Swab					
	% Prevalence (Number Positive/Number Tested)						% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]		CT+/ NG+		CT+/ NG –[b]		CT –/ NG+[b]	
1	0.0	(0/40)	0.0	(0/40)	0.0	(0/40)	0.0	(0/41)	0.0	(0/41)	0.0	(0/41)
3	1.5	(2/134)	4.5	(6/134)	0.7	(1/134)	2.3	(3/130)	3.8	(5/130)	0.8	(1/130)
4	0.0	(0/26)	7.7	(2/26)	0.0	(0/26)	0.0	(0/26)	15.4	(4/26)	0.0	(0/26)
5	0.0	(0/16)	0.0	(0/16)	0.0	(0/16)	0.0	(0/17)	0.0	(0/17)	0.0	(0/17)
6	0.0	(0/9)	11.1	(1/9)	0.0	(0/9)	0.0	(0/8)	12.5	(1/8)	0.0	(0/8)
7	3.8	(9/238)	9.2	(22/238)	3.8	(9/238)	3.9	(9/230)	10.0	(23/230)	3.9	(9/230)
8	0.0	(0/46)	8.7	(4/46)	4.3	(2/46)	0.0	(0/47)	10.6	(5/47)	4.3	(2/47)
9	5.6	(3/54)	14.8	(8/54)	3.7	(2/54)	4.3	(2/47)	12.8	(6/47)	6.4	(3/47)
10	1.9	(3/162)	11.1	(18/162)	1.9	(3/162)	2.6	(4/152)	13.8	(21/152)	2.0	(3/152)
11	1.1	(3/261)	7.3	(19/261)	1.5	(4/261)	1.2	(3/258)	7.4	(19/258)	1.6	(4/258)
12	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)
13	0.0	(0/61)	0.0	(0/61)	0.0	(0/61)	0.0	(0/59)	0.0	(0/59)	0.0	(0/59)
14	0.0	(0/75)	1.3	(1/75)	1.3	(1/75)	0.0	(0/72)	2.8	(2/72)	0.0	(0/72)
15	1.9	(1/53)	0.0	(0/53)	0.0	(0/53)	1.9	(1/52)	0.0	(0/52)	0.0	(0/52)
16	0.0	(0/22)	0.0	(0/22)	4.5	(1/22)	0.0	(0/23)	4.3	(1/23)	4.3	(1/23)
All	1.7	(21/1208)	6.7	(81/1208)	1.9	(23/1208)	1.9	(22/1173)	7.4	(87/1173)	2.0	(23/1173)

[a] No evaluable results were available from Site 2.
[b] Does not include specimens that were positive for both CT and NG.

Table 3.24

Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site: Symptomatic and Asymptomatic Female Urine Specimens

	Female Urine % Prevalence (Number Positive/Number Tested)					
Site	**CT+/ NG+**		**CT+/ NG –[a]**		**CT –/ NG+[b]**	
1	0.0	(0/60)	0.0	(0/60)	0.0	(0/60)
3	1.8	(3/165)	3.6	(6/165)	1.8	(3/165)
4	0.0	(0/49)	8.2	(4/49)	2.0	(1/49)
5	0.0	(0/21)	0.0	(0/21)	0.0	(0/21)
6	0.0	(0/15)	6.7	(1/15)	6.7	(1/15)
7	3.1	(9/293)	8.5	(25/293)	3.8	(11/293)
8	0.0	(0/57)	7.0	(4/57)	3.5	(2/57)
9	4.6	(3/65)	15.4	(10/65)	4.6	(3/65)
10	2.4	(4/168)	11.3	(19/168)	1.8	(3/168)
11	1.4	(4/284)	8.8	(25/284)	2.1	(6/284)
12	0.0	(0/11)	0.0	(0/11)	0.0	(0/11)
13	0.0	(0/70)	0.0	(0/70)	0.0	(0/70)
14	0.0	(0/79)	2.5	(2/79)	0.0	(0/79)
15	1.7	(1/59)	0.0	(0/59)	0.0	(0/59)
16	0.0	(0/26)	0.0	(0/26)	3.8	(1/26)
All	1.7	(24/1422)	6.8	(96/1422)	2.2	(31/1422)

[a] No evaluable results were available from Site 2.
[b] Does not include specimens that were positive for both CT and NG.

Table 3.25

Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site: Symptomatic Male Urethral Swab

	Urethral Swab					
	% Prevalence (Number Positive/Number Tested)					
Site[a,b]	CT+/ NG+		CT+/ NG –[c]		CT –/ NG+[c]	
3	12.0	(10/83)	12.0	(10/83)	16.9	(14/83)
4	5.6	(2/36)	2.8	(1/36)	8.3	(3/36)
5	0.0	(0/22)	9.1	(2/22)	4.5	(1/22)
6	0.0	(0/6)	16.7	(1/6)	16.7	(1/6)
7	11.1	(9/81)	17.3	(14/81)	17.3	(14/81)
8	7.5	(11/147)	15.6	(23/147)	21.1	(31/147)
9	11.4	(17/149)	13.4	(20/149)	38.3	(57/149)
10	5.5	(4/73)	17.8	(13/73)	13.7	(10/73)
12	0.0	(0/3)	0.0	(0/3)	0.0	(0/3)
13	0.0	(0/24)	0.0	(0/24)	0.0	(0/24)
14	0.0	(0/14)	0.0	(0/14)	14.3	(2/14)
15	0.0	(0/6)	0.0	(0/6)	0.0	(0/6)
16	3.7	(1/27)	0.0	(0/27)	14.8	(4/27)
All	8.0	(54/671)	12.5	(84/671)	20.4	(137/671)

[a] Male specimens were not collected from Site 1.
[b] No symptomatic male urethral swab specimens were available from Site 2 or 11.
[c] Does not include specimens that were positive for both CT and NG.

Table 3.26

Prevalence of *C. trachomatis* and/or *N. gonorrhoeae* by Collection Site: Symptomatic and Asymptomatic Male Urine Specimens

	Urine					
	% Prevalence (Number Positive/Number Tested)					
Site[a]	CT+/ NG+		CT+/ NG–[b]		CT –/ NG+[b]	
2	0.0	(0/6)	0.0	(0/6)	0.0	(0/6)
3	15.1	(26/172)	8.7	(15/172)	9.9	(17/172)
4	4.2	(4/96)	6.3	(6/96)	7.3	(7/96)
5	0.0	(0/35)	5.7	(2/35)	2.9	(1/35)
6	0.0	(0/41)	22.0	(9/41)	2.4	(1/41)
7	6.7	(12/179)	16.8	(30/179)	10.1	(18/179)
8	5.2	(15/290)	15.2	(44/290)	12.4	(36/290)
9	10.1	(21/208)	20.7	(43/208)	30.8	(64/208)
10	1.4	(2/145)	20.7	(30/145)	8.3	(12/145)
11	0.0	(0/2)	100.0	(2/2)	0.0	(0/2)
12	0.0	(0/3)	0.0	(0/3)	0.0	(0/3)
13	0.0	(0/60)	1.7	(1/60)	0.0	(0/60)
14	0.0	(0/76)	1.3	(1/76)	2.6	(2/76)
15	0.0	(0/53)	3.8	(2/53)	0.0	(0/53)
16	0.0	(0/101)	1.0	(1/101)	5.9	(6/101)
All	5.5	(80/1467)	12.7	(186/1467)	11.2	(164/1467)

[a] Male specimens were not collected from Site 1.
[b] Does not include specimens that were positive for both CT and NG.

Table 3.27

Positive and Negative Predictive Values for Hypothetical Prevalence Rates for *Chlamydia trachomatis*

Prevalence Rate (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
0.5	95.2	99.3	40.6	100.0
1.0	95.2	99.3	57.9	100.0
2.0	95.2	99.3	73.5	99.9
5.0	95.2	99.3	87.7	99.7
10.0	95.2	99.3	93.8	99.5
15.0	95.2	99.3	96.0	99.2
20.0	95.2	99.3	97.1	98.8
25.0	95.2	99.3	97.8	98.4
30.0	95.2	99.3	98.3	98.0

Table 3.28

Positive and Negative Predictive Values for Hypothetical Prevalence Rates for *Neisseria gonorrhoeae*

Prevalence Rate (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
0.5	97.5	99.7	62.0	100.0
1.0	97.5	99.7	76.7	100.0
2.0	97.5	99.7	86.9	99.9
5.0	97.5	99.7	94.5	99.9
10.0	97.5	99.7	97.3	99.7
15.0	97.5	99.7	98.3	99.6
20.0	97.5	99.7	98.8	99.4
25.0	97.5	99.7	99.1	99.2
30.0	97.5	99.7	99.3	98.9

3.16 Conclusion Drawn from Clinical Studies

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Silver Spring, MD 20993-0002

MAY 2 8 2010

Abbott Molecular, Inc..
c/o Paula Martin
Senior Manager, Regulatory and Clinical Affairs
1300 E. Touhy Ave.
Des Plaines, IL 60018

Re: k092704

Trade/Device Name:	Abbott RealTime CT/NG assay
Regulation Number:	21CFR §866.3390 and 21CFR §866.3120
Regulation Name:	In vitro polymerase chain reaction (PCR) assay for *Chlamydia trachomatis* and *Neisserua gonorrhoeae* and Microbiological Specimen Collection and Transport Device
Regulatory Class:	Class I, Class II
Product Code:	LSL, MKZ
Dated:	May 21, 2010
Received:	May 24, 2010

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications of Use

510(k) Number: K092704
Device Name: Abbott RealTi*m*e CT/NG assay

The proposed intended use for the Abbott RealTi*m*e CT/NG assay is:

The Abbott RealTi*m*e CT/NG (List No. 8L07-91) assay is an in vitro polymerase chain reaction (PCR) assay for the direct, qualitative detection of the plasmid DNA of *Chlamydia trachomatis* and the genomic DNA of *Neisseria gonorrhoeae.* The assay may be used to test the following specimens from symptomatic individuals: female endocervical swab, clinician-collected vaginal swab, and patient-collected vaginal swab specimens; male urethral swab specimens; and female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected vaginal swab and patient-collected vaginal swab specimens; female and male urine specimens.

Prescription Use **X** AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.119) (Per 21 CFR Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety